## H. R. 2697

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health with respect to research and related activities concerning osteoporosis and related bone diseases.

## IN THE HOUSE OF REPRESENTATIVES

October 22, 1997

Ms. Eddie Bernice Johnson of Texas (for herself, Mrs. Maloney of New York, Mrs. Morella, Ms. Woolsey, Mr. Pascrell, Mr. Dellums, and Mr. Dingell) introduced the following bill; which was referred to the Committee on Commerce

## A BILL

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health with respect to research and related activities concerning osteoporosis and related bone diseases.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Osteoporosis and Re-
- 5 lated Bone Diseases Research Act of 1997".
- 6 SEC. 2. FINDINGS.
- 7 The Congress finds that—

- 1 (1) osteoporosis, or porous bone, is a condition 2 characterized by an excessive loss of bone tissue and 3 an increased susceptibility to fractures of the hip, 4 spine, and wrist;
  - (2) osteoporosis is a threat to an estimated 28,000,000 Americans, 80 percent of whom are women, many of whose cases go undiagnosed because the condition develops without symptoms until a strain, bump, or fall causes a fracture;
  - (3) between 3 and 4 million Americans have Paget's disease, osteogenesis imperfecta, hyperparathyroidism, and other related metabolic bone diseases;
  - (4) osteoporosis is responsible for 1,500,000 bone fractures annually, including more than 300,000 hip fractures, 700,000 vertebral fractures, 200,000 fractures of the wrist, and the remaining fractures at other sites;
  - (5) 1 of every 2 women and 1 of every 8 men over age 50 will develop fractures associated with osteoporosis in their lifetimes;
  - (6) direct medical costs of osteoporosis are estimated to be \$13,800,000,000 annually for the United States, not including the costs of family care and lost work for caregivers;

- (7) direct medical costs of osteoporosis are expected to increase precipitously because the proportion of the population comprised of older persons is expanding and each generation of older persons tends to have a higher incidence of osteoporosis than preceding generations;
  - (8) technology now exists, and new technology is developing, that will permit early diagnosis and prevention of osteoporosis as well as management of the condition once it has developed;
  - (9) funding for research on osteoporosis and related bone diseases is severely constrained at key research institutes, including the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Dental Research, and the National Institute of Child Health and Human Development;
  - (10) further research is needed to improve medical knowledge concerning—
    - (A) cellular mechanisms related to the processes of bone resorption and bone formation, and the effect of different agents on bone remodeling;

| 1  | (B) risk factors for osteoporosis, including       |
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| 2  | newly discovered risk factors, risk factors relat- |
| 3  | ed to groups not ordinarily studied (such as       |
| 4  | men and minorities), risk factors related to       |
| 5  | genes that help to control skeletal metabolism,    |
| 6  | and risk factors relating to the relationship of   |
| 7  | aging processes to the development of              |
| 8  | osteoporosis;                                      |
| 9  | (C) bone mass measurement technology,              |
| 10 | including more widespread and cost-effective       |
| 11 | techniques for making more precise measure-        |
| 12 | ments and for interpreting measurements;           |
| 13 | (D) calcium (including bioavailability, in-        |
| 14 | take requirements, and the role of calcium in      |
| 15 | building heavier and denser skeletons), and vi-    |
| 16 | tamin D and its role as an essential vitamin in    |
| 17 | adults;  |
| 18 | (E) prevention and treatment, including            |
| 19 | the efficacy of current therapies, alternative     |
| 20 | drug therapies for prevention and treatment,       |
| 21 | and the role of exercise; and                      |
| 22 | (F) rehabilitation; and                            |
| 23 | (11) further educational efforts are needed to     |
| 24 | increase public and professional knowledge of the  |

- 1 causes of, methods for avoiding, and treatment of
- 2 osteoporosis.

## 3 SEC. 3. OSTEOPOROSIS RESEARCH.

- 4 Subpart 4 of part C of title IV of the Public Health
- 5 Service Act (42 U.S.C. 285d et seq.) is amended by adding
- 6 at the end the following new section:
- 7 "RESEARCH ON OSTEOPOROSIS AND RELATED DISEASES
- 8 "Sec. 442A. (a) Expansion of Research.—The
- 9 Director of the Institute, the Director of the National In-
- 10 stitute on Aging, the Director of the National Institute
- 11 of Diabetes and Digestive and Kidney Diseases, the Direc-
- 12 tor of the National Institute of Dental Research, and the
- 13 Director of the National Institute of Child Health and
- 14 Human Development shall expand and intensify research
- 15 on osteoporosis and related bone diseases. The research
- 16 shall be in addition to research that is authorized under
- 17 any other provision of law.
- 18 "(b) Mechanisms for Expansion of Research.—
- 19 Each of the Directors specified in subsection (a) shall, in
- 20 carrying out such subsection, provide for one or more of
- 21 the following:
- "(1) Investigator-initiated research.
- "(2) Funding for investigators beginning their
- research careers.
- 25 "(3) Mentorship research grants.
- 26 "(c) Specialized Centers of Research.—

| 1  | "(1) In General.—The Director of the Insti-            |
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| 2  | tute, after consultation with the advisory council for |
| 3  | the Institute, shall make grants to, or enter into     |
| 4  | contracts with, public or nonprofit private entities   |
| 5  | for the development and operation of centers to con-   |
| 6  | duct research on osteoporosis and related bone dis-    |
| 7  | eases. Subject to the extent of amounts made avail-    |
| 8  | able in appropriations Acts, the Director shall pro-   |
| 9  | vide for not less than three such centers.             |
| 10 | "(2) Activities.—Each center assisted under            |
| 11 | this subsection—                                       |
| 12 | "(A) shall, with respect to osteoporosis and           |
| 13 | related bone diseases—                                 |
| 14 | "(i) conduct basic and clinical re-                    |
| 15 | search;  |
| 16 | "(ii) develop protocols for training                   |
| 17 | physicians, scientists, nurses, and other              |
| 18 | health and allied health professionals;                |
| 19 | "(iii) conduct training programs for                   |
| 20 | such individuals;                                      |
| 21 | "(iv) develop model continuing edu-                    |
| 22 | cation programs for such professionals;                |
| 23 | and  |
| 24 | "(v) disseminate information to such                   |
| 25 | professionals and the public;                          |

| 1  | "(B) may use the funds to provide stipends                |
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| 2  | for health and allied health professionals en-            |
| 3  | rolled in training programs described in sub-             |
| 4  | paragraph (A)(iii); and                                   |
| 5  | "(C) shall use the facilities of a single in-             |
| 6  | stitution, or be formed from a consortium of co-          |
| 7  | operating institutions, meeting such require-             |
| 8  | ments as may be prescribed by the Director of             |
| 9  | the Institute.  |
| 10 | "(3) Duration of Support of a                             |
| 11 | center under this subsection may be for a period not      |
| 12 | exceeding 5 years. Such period may be extended for        |
| 13 | one or more additional periods not exceeding 5 years      |
| 14 | if the operations of such center have been reviewed       |
| 15 | by an appropriate technical and scientific peer re-       |
| 16 | view group established by the Director and if such        |
| 17 | group has recommended to the Director that such           |
| 18 | period should be extended.                                |
| 19 | "(d) Definition of Related Bone Diseases.—                |
| 20 | For purposes of this section, the term 'related bone dis- |
| 21 | eases' includes—  |
| 22 | "(1) Paget's disease, a bone disease character-           |
| 23 | ized by enlargement and loss of density with bowing       |

and deformity of the bones;

| 1  | "(2) osteogenesis imperfecta, a familial disease      |
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| 2  | marked by extreme brittleness of the long bones;      |
| 3  | "(3) hyperparathyroidism, a condition charac-         |
| 4  | terized by the presence of excess parathormone in     |
| 5  | the body resulting in disturbance of calcium metabo-  |
| 6  | lism with loss of calcium from bone and renal dam-    |
| 7  | age;  |
| 8  | "(4) hypoparathyroidism, a condition character-       |
| 9  | ized by the absence of parathormone resulting in      |
| 10 | disturbances of calcium metabolism;                   |
| 11 | "(5) renal bone disease, a disease characterized      |
| 12 | by metabolic disturbances from dialysis, renal trans- |
| 13 | plants, or other renal disturbances;                  |
| 14 | "(6) primary or postmenopausal osteoporosis           |
| 15 | and secondary osteoporosis, such as that induced by   |
| 16 | corticosteroids; and                                  |
| 17 | "(7) other general diseases of bone and mineral       |
| 18 | metabolism including abnormalities of vitamin D.      |
| 19 | "(e) Authorizations of Appropriations.—               |
| 20 | "(1) National institute of arthritis and              |
| 21 | MUSCULOSKELETAL AND SKIN DISEASES.—For the            |
| 22 | purpose of carrying out this section through the Na-  |
| 23 | tional Institute of Arthritis and Musculoskeletal and |
| 24 | Skin Diseases, there are authorized to be appro-      |
| 25 | priated \$17,000,000 for each of the fiscal years     |

- 1 1999 through 2001, and such sums as may be nec-2 essary for each subsequent fiscal year.
- "(2) National institute on aging.—For the purpose of carrying out this section through the National Institute on Aging, there are authorized to be appropriated \$10,000,000 for each of the fiscal years 1999 through 2001, and such sums as may be necessary for each subsequent fiscal year.
  - "(3) NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES.—For the purpose of carrying out this section through the National Institute of Diabetes and Digestive and Kidney Diseases, there are authorized to be appropriated \$10,000,000 for each of the fiscal years 1999 through 2001, and such sums as may be necessary for each subsequent fiscal year.
  - "(4) National Institute of Dental Research.—For the purpose of carrying out this section through the National Institute of Dental Research, there are authorized to be appropriated \$5,000,000 for each of the fiscal years 1999 through 2001, and such sums as may be necessary for each subsequent fiscal year.
- 24 "(5) NATIONAL INSTITUTE OF CHILD HEALTH
  25 AND HUMAN DEVELOPMENT.—For the purpose of

carrying out this section through the National Institute of Child Health and Human Development, there are authorized to be appropriated \$5,000,000 for each of the fiscal years 1999 through 2001, and such sums as may be necessary for each subsequent fiscal year.

"(6) Specialized centers of research.—
For the purpose of carrying out subsection (c), there are authorized to be appropriated \$3,000,000 for each of the fiscal years 1999 through 2001, and such sums as may be necessary for each subsequent fiscal year.

"(7) Relation to other provisions.—Authorizations of appropriations under this subsection are in addition to amounts authorized to be appropriated for biomedical research relating to osteoporosis and related bone diseases under any other provision of law.".

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